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(54) METHOD OF CONTROLLING A VENTILATION APPARATUS

(71) We, DRÄGERWERK AKTIENGESELLSCHAFT, a German company, of Moislinger Allee 53/55, 24 Lubeck 1, Federal Republic of Termany, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a method of controlling output magnitudes of a ventilation apparatus according to physiological parameters sensed on the patient under ventilation by sensing means as well as to a ventilation installation for performing this method.

By means of a ventilation apparatus, there is maintained for the patient under ventilation that respiratory exchange, either provided or desired for him, of oxygen (O_2) and carbon dioxide (CO_2). The optimum adaptation to the patient under ventilation is of the utmost importance in this respect.

There is known a ventilation apparatus allowing by means of servo-valves which are controlled electronically, to control the apparatus output magnitudes, according to the measured magnitudes sensed from the patient under ventilation. In a known method use is then made, as a physiological parameter for the control action, of the partial oxygen pressure of the arterial blood of the patient under ventilation. The voltages continuously applied to a sensing amplifier for paO_2, are transmitted to an amplifier which compares the momentary voltage to a set value which is adjusted across a potentiometer. The latter amplifier controls, through a delay component and according to the voltage differentials between the predetermined set value and the actual measured voltage, a particular output magnitude of the ventilation apparatus. The known embodiment has the drawback that the cause of the variation from the actual value is not diagnosed in such a way that in case of need, there could be performed a non-physiological control of the output magnitudes of the ventilation apparatus (Methodik der Beatmung by V. Schulz, in Intensivmedizin, 13, pp 133–147, 1976).

There is further known a ventilation apparatus which is controlled by the data obtained from the patient under ventilation, comprising a meter which measures at least the compliance and resistance of the respiratory tracts more than once for each inhaling and exhaling phase and thus provides pulmonary function data, and a control installation with a computing section and a monitoring section selecting measuring values to be determined and providing, during the following portion of the inhaling phase or the exhaling phase, an amount of respiratory gas which is determined by the computing section according to the changes in the directly preceding portion of the inhaling or exhaling phase.

The ventilation apparatus can further comprise an analyser for the gaseous blood components, which is also connected to the ventilation apparatus. The control and monitoring unit regulates the respiratory gas amount as well as the composition thereof. However, said ventilation apparatus does not allow obtaining of information about all of the parameters for advantageously insuring an optimum adaptation to the patient under ventilation. (German application open to reading DT-OS 25 05 670.6.)

From a publication, it has been indicated in the field of scientific research that it is possible to obtain additional information regarding important physiological parameters for diagnostic purposes by deliberately disturbing for a short time the composition of the inhaled gas mixture and by measuring the response at the level of the exhaled gas mixture. It is not possible to observe said physiological parameters with "passive" methods of direct measuring, in other words by measuring changes in the parameters occurring solely owing to changes in the condition of the patient. (A method to estimate pulmonary gas volume, distribution of ventilation and pulmonary capillary blood-flow in intensive care— by M. Demeester et al, excerpt from "Computers in cardiology" copyright 1975 by the Institute of Electrical and Electronics Engineers Inc.)

According to one aspect of the present invention, there is provided a method of controlling output magnitudes of a ventilation apparatus according to physiological parameters sensed on a patient under ventilation by sensing means, in which changes in the physiological parameters occurring owing to changes in the

condition of the patient are monitored and are used automatically in controlling the ventilation apparatus, at least one output magnitude of the ventilation apparatus is deliberately disturbed in a predetermined and repeated manner, and the additional changes in the physiological parameters occurring owing to those disturbances are monitored and are used automatically in controlling the ventilation apparatus.

According to another aspect of the present invention, there is provided ventilation installation including a device for controlling output magnitudes of a ventilation apparatus according to physiological parameters sensed on a patient under ventilation by sensing means, said device comprising controlling means for controlling the ventilation apparatus, monitoring means for actuating said controlling means in dependence on changes in the physiological parameters occurring owing to changes in the condition of the patient, pilot means which serves to disturb deliberately in a predetermined and repeated manner at least one output magnitude of the ventilation apparatus, and other means arranged to use the additional changes in the physiological parameters occurring owing to these disturbances to actuate said controlling means.

The invention has the advantage that besides controlling the ventilation apparatus in dependence on the "passive" changes in the physiological parameters, that is without the patient under ventilation being subjected to any action, the controlling is also performed in dependence on "active" changes in the physiological parameters resulting from deliberate reproducible disturbances in the output magnitudes of the ventilation apparatus. This offers the possibility of not making use of the one output magnitude which would have been systematically bound to one of the physiological parameters, but by means of the present method it is now possible to select from among the output magnitudes, one individually or a combination thereof in an optimum way for the patient under ventilation and to modify said magnitude or magnitudes accordingly.

As output magnitudes from the ventilation apparatus which can be changed during the disturbances (also called "functional tests"), it is possible to consider for instance the tidal volume, the ventilation frequency, the inhaling or exhaling flow-rate, the flow pattern, the ratio of the inhaling time to the exhaling time, the period of the inhaling pause, or the inhaling or exhaling pressure, *e.g.* the positive end expiratory pressure (PEEP).

In a particularly advantageous embodiment, an output magnitude of the ventilation apparatus which can be disturbed is the gas mixture composition as supplied by the ventilation apparatus. An important physiological parameter of the patient under ventilation which is easy to deduce therefrom is the functional residual capacity (*i.e.* the capacity of the lungs in the normal exhalation situation), which is advantageously ascertained for an optimum adjustment of the pressure at the end of exhalation.

The variation with time of the deliberate change of an output magnitude can be of any kind in principle, for example of a sinusoidal, stepped, saw-tooth or triangular shape.

It is particularly advantageous that the disturbance be present as a burst, that is a sudden variation of relatively short duration.

This allows ascertainment also of those physiological variables which react with a short time constant to the disturbance, for controlling the ventilation apparatus. Such a fast-reacting physiological parameter is the gas exchange inside the lungs.

If use is made of the respiratory mixture composition as magnitude to be disturbed, any respiratory mixture component, e.g. nitrogen, helium, carbon monoxide, xenon, krypton, or deuterium, can be used for this purpose.

It is particularly advantageous to use for this purpose the oxygen and carbon dioxide components, both of these gases having no physiological drawbacks and being easily sensed. In such as case, both said gas components can be changed either separately or simultaneously.

The determined disturbance in the output magnitude(s) of the ventilation apparatus should occur at extremely long time intervals relative to the disturbance period.

It is advantageous that the time interval between the determined disturbances is chosen in a fixed way, every 40 minutes for example.

It is particularly advantageous that the determined disturbance be also triggered when the passive changes resulting from the patient's condition under ventilation lie outside a predetermined tolerance range or a predicted development.

It is then possible to adjust rapidly the control of the ventilation apparatus when changes in the condition of the patient under ventilation occur. Such a method is particularly advantageous because the continuous measuring of a physiological mangitude in combination with the change thereof caused by the determined disturbance allows a physiologically-optimized control of the output magnitudes from the ventilation apparatus. For instance the positive end expiratory pressure (PEEP) can be monitored and controlled relative to the functional residual capacity, the respiratory exchanges and the lun perfusion (i.e. the pulmonary blood flow through the pulmonary tissue). The method further allows a control of the inspiratory oxygen concentration according to the actual requirements at any moment for the patient under ventilation while taking into account disturbing factors such as a faulty perfusion and an unblanced distribution of ventilation.

For the performing of the method, the installation comprises a pilot unit for the

execution of the functional test at preselected values changing the output magnitudes of the ventilation apparatus in a determined way, as well as a functional evaluation unit in which the essential measuring data resulting from the change are recorded, utilized and transmitted to a monitoring unit of the ventilation apparatus.

In order that the invention may be clearly understood and readily carried into effect, reference will now be made, by way of example, to the accompanying drawing, which shows a block diagram of a ventilation installation.

The installation comprises a ventilation apparatus 7 which is comprised of a monitorable gas mixer 8 and a control and monitoring device 9. The device 9 as well as the monitorable gas mixer 8 are controlled by a master monitoring unit 10 which receives in turn control signals from a pilot unit 1 for the execution of a functional test and a device 5 for analysing the gaseous components of the blood. The measuring data originating from the pulmonary function meter 4 as well as from the blood gas component analyzer 5 are coupled to a functional evaluating unit 2, the output signal of which is transmitted to the master monitoring unit 10 as well as to a display unit 3. The unit 2 is substantially a computer which from the dynamic pattern of the data issuing from the meter 4 and the analyser 5 for directly measurable patient parameters calculates patient parameters which are not directly measurable. The display unit 3 also serves to display the measuring data from the meter 4 and the analyzer 5. The unit 2 may have a recording function independently of the unit 3 in cases where it would be easier as regards an operator's reading and supervision ability to indicate on the unit 3 only the directly measured data and the data derived from "passive" changes and to indicate on the unit 2 only data derived from the functional tests. The pulmonary function meter 4 measures the parameters of the pulmonary mechanics of the patient 6 under ventilation, while the blood gas component analyzer 5 analyzes the blood as regards the carbon dioxide and oxygen components thereof.

The ventilation installation works as follows: the ventilation apparatus 7 supplies the patient 6 with respiratory gas. The gas composition is a function of the input magnitudes which the master monitoring unit 10 supplies to the monitorable gas mixer 8. The other output magnitudes from the ventilation apparatus 7 are functions of input magnitudes which the device 9 receives from the master monitor unit 10. The values for the gas components of the blood of the patient under ventilation are measured by the blood gas component analyzer 5 and fed as monitoring signal to the master unit 10 as well as to the functional evaluation unit 2. The parameters of the patient's pulmonary mechanics are also sensed by the pulmonary function meter 4 and fed as monitoring signal to the master unit 10 as well as to the functional evaluation unit 2. The passive changes in the physiological parameters sensed by the meter 4 and the analyzer 5 are used at least at predetermined time intervals and preferably continuously to control the ventilation apparatus 7 *via* the master monitoring unit 10. The pilot unit 1 for the execution of the functional test triggers at determined time intervals, for instance every 40 minutes, through the master unit 10, the monitorable gas mixer 8 and the ventilation apparatus 7, a change in the respiratory gas composition and other output magnitudes from the ventilation apparatus 7, during a short time, for example some ten respiratory cycles. The pilot unit 1 simultaneously triggers, *via* the unit 10, operation of the functional evaluating unit 2. This change results for the patient 6 in a characteristic change in the values of his blood gas components which are measured by the analyzer 5 and which are available as input signal for the functional evaluation unit 2. This also causes in the patient under ventilation characteristic changes in the exhaled gases which are measured by the pulmonary function meter 4 and similarly available for the functional evaluation unit 2. From these signals obtained during a short change triggered by the pilot unit in the respiratory gas composition and said other output magnitudes, the functional evaluation unit 2 computes, independently of those control signals present during the normal ventilation which originate from the pulmonary function meter 4 and the blood gas component analyzer 5, its own monitoring signals for the master unit 10. The unit 10 then controls through the monitorable gas mixer 8 or, according to the condition of the patient under ventilation, also through the control and monitoring device 9, the output magnitudes from the ventilation apparatus 7.

When substantial changes in the condition of the patient under ventilation occur, such changes appear in the display unit 3 and the supervising personnel can then trigger by hand, through the pilot unit 1, a deliberate disturbance of output magnitudes of the ventilation apparatus 7.

WHAT WE CLAIM IS:—

1. A method of controlling output magnitudes of a ventiltion apparatus according to physiological parameters sensed on a patient under ventilation by sensing means, in which changes in the physiological parameters occurring owing to changes in the condition of the patient are monitored and are used automatically in controlling the ventilation apparatus, at least one output magnitude of the ventilation apparatus is deliberately disturbed in a predetermined and repeated manner, and the additional changes in the physiological parameters occurring owing to these disturbances are monitored and are used automatically in controlling the ventilation apparatus.

2. A method as claimed in claim 1, in

which a deliberately disturbed output magnitude is comprised of the composition of the respiratory mixture as supplied by the ventilation apparatus.

3. A method as claimed in claim 2 in which a deliberately disturbed output magnitude is comprised of the O_2 component of the respiratory mixture as supplied by the ventilation apparatus.

4. A method as claimed in claim 2 or 3 in which a deliberately disturbed output magnitude is comprised of a CO_2 component of the respiratory mixture as supplied by the ventilation apparatus.

5. A method as claimed in any preceding claim, in which the time intervals between the disturbances are relatively long and each disturbance takes the form of a sudden variation of relatively short duration.

6. A method as claimed in any preceding claim, in which the time intervals between the disturbances are fixed beforehand.

7. A method as claimed in any preceding claim, in which additionally such deliberate disturbance is triggered when the first-mentioned changes in the physiological parameters lie outside a predetermined tolerance range or a predicted development.

8. Ventilation installation including a device for controlling output magnitudes of a ventilation apparatus according to physiological parameters sensed on a patient under ventilation by sensing means, said device comprising controlling means for actuating said controlling means in dependence on changes in the physiological parameters occurring owing to changes in the condition of the patient, pilot means which serves to disturb deliberately in a predetermined and repeated manner at least one output magnitude of the ventilation apparatus, and other means arranged to use the additional changes in the physiological parameters occurring owing to these disturbances to actuate said controlling means.

9. A method of controlling output magnitudes of a ventilation apparatus, substantially as hereinbefore described with reference to the accompanying drawing.

10. Ventilation installation, substantially as hereinbefore described with reference to the accompanying drawing.

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1 SHEET *This drawing is a reproduction of the Original on a reduced scale*